

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: February 11, 2011

Submitter: GE Healthcare
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Device: Trade Name: Centricity PACS

Common/Usual Name: PACS, Picture Archiving and Communication System

Classification Names: 21 CFR 892.2050 System, Image Processing, Radiological

Product Code: LLZ

Secondary Product Code: GCJ
876.1500 Endoscope and accessories

Predicate Device(s): K043415 Centricity™ PACS

Device Description: Centricity PACS is an enterprise grade Picture Archiving and Communications System (PACS) for managing digital medical images and associated data. Centricity PACS enables the storage, retrieval, distribution, printing, and presentation of images acquired from diagnostic imaging modalities.

Centricity PACS is a standards-based, customizable, and scalable solution supporting several of the Integrating the Healthcare Enterprise (IHE) profiles, Digital Imaging and Communications in Medicine (DICOM), and the Health Level Seven (HL7) protocol standards for managing digital medical images and patient data. Centricity PACS supports radiographic imaging-as in clinical radiography, cardiology, dentistry, and mammography and non-radiologic imaging, including video support.

Intended Use: Centricity PACS software product is intended for the storage, reading, diagnostic review, analysis, annotation, distribution, printing, editing, and processing of digital images and data acquired from diagnostic imaging devices.

The Centricity PACS Workstation software is intended for use as a primary diagnostic and analysis tool for diagnostic images by trained healthcare professionals, including radiologists, physicians, technologists, clinicians and nurses. It is also intended for use as a clinical review workstation throughout the healthcare facility.

Technology: Centricity PACS employs the same fundamental scientific technology as its predicate devices.

<u>Summary of Technological Characteristics:</u>	Predicate Device Centricity PACS K043415 (v2.1)	Proposed Device Centricity PACS 3.2.1
DESIGN	<p>Centricity PACS is a software product with optional turnkey solution for hardware components.</p> <p>Centricity PACS is a standards-based, customizable, and scalable solution supporting several of the Integrating the Healthcare Enterprise (IHE) profiles, Digital Imaging and Communications in Medicine (DICOM), and the Health Level Seven (HL7) protocol standards for managing digital medical images and patient data.</p> <p>Centricity PACS supports radiographic imaging-as in clinical radiography, cardiology, dentistry, and mammography and non-radiologic imaging, including video support.</p>	<p>Centricity PACS v3.2.1 employs the same fundamental scientific technology as its predicate devices, however v3.2.1 is a software only product.</p> <p>Centricity PACS is a standards-based, customizable, and scalable solution supporting several of the Integrating the Healthcare Enterprise (IHE) profiles, Digital Imaging and Communications in Medicine (DICOM), and the Health Level Seven (HL7) protocol standards for managing digital medical images and patient data.</p> <p>Centricity PACS supports radiographic imaging-as in clinical radiography, cardiology, dentistry, and mammography and non-radiologic imaging, including video support.</p>
Material	Not Applicable – Centricity PACS is a software product, and therefore, has no specific materials of manufacture.	Not Applicable – Like the predicate product, the Centricity PACS v3.2.1, is a software only product, and therefore, has no specific materials of manufacture.
Chemical Composition	Not Applicable – Centricity PACS is a software product, and therefore, has no specific chemical composition.	Not Applicable – Like the predicate product, the Centricity PACS v3.2.1, is a software only product, and therefore, has no specific chemical composition.
Energy Source	Not Applicable – Centricity PACS is a software product, and therefore, has no Energy Source.	Not Applicable – Like the predicate product, the Centricity PACS v3.2.1, is a software only product, and therefore, has no Energy Source.

<u>Determination of Substantial Equivalence:</u>	<u>Summary of Non-Clinical Tests:</u> Centricity PACS comply with voluntary standards as detailed in Section 9 of this premarket submission. The following quality assurance measures were applied to the development of the system: <ul style="list-style-type: none">• Risk Analysis• Requirements Reviews• Design Reviews• Testing on unit level (Module verification)• Integration testing (System verification)• Performance testing (Verification)• Safety testing (Verification)• Simulated use testing (Validation)
<u>Conclusion:</u>	<u>Summary of Clinical Tests:</u> The subject of this premarket submission, Centricity PACS, did not require clinical studies to support substantial equivalence. GE Healthcare considers Centricity PACS to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

GE Healthcare
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

MAY - 5 2011

Re: K110875

Trade/Device Name: Centricity PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ and GCJ
Dated: March 29, 2011
Received: March 30, 2011

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

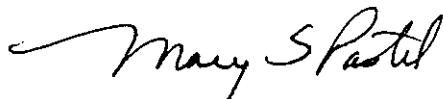
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

FDA CDRH DMC *K56*

510(k) Number (if known): _____

MAR 30 2011

Received 

Device Name: Centricity PACS

Indications for Use:

The Centricity PACS provides scalable image and data management solutions for medical imaging modalities, such as Computed Tomography (CT), Magnetic Resonance (MR), Computed Radiography (CR), Digital X-Ray (DX), Digital Mammography (MG), Ultrasound (US), Nuclear Medicine (NM), Positron Emission Tomography (PET), X-Ray Angiography (XA), Oral X-Ray (IO), Endoscopic Video (ES), and any other DICOM devices.

The workstation interface software provides the user with a means to display, manipulate, archive, print, and export images when connected with the Centricity PACS infrastructure.

To be viewed for primary interpretation, the digital mammography images must be acquired from an FDA approved Full Field Digital Mammography (FFDM) device for primary interpretation. Furthermore, the FFDM must be able to provide, to the Centricity PACS, a viewable DICOM 'for presentation' mammography image as approved by the FDA for primary interpretation. Images that are printed to film must be printed using a FDA approved printer for the diagnosis of digital mammography images.

To be viewed for primary diagnosis, digital mammography images must be viewed on a display system that has been cleared by the FDA for the diagnosis of digital mammography images.

The Centricity PACS allows integration with other open interfaces, such as DICOM, to web client products and archive devices.

The Centricity Infrastructure software provides for the system's database and image management, printing, HL-7 interfacing, and all DICOM services including but not limited to, Store, Print, Query/Retrieve, and Send.

It is the user's responsibility to ensure quality, ambient light conditions, and image compression ratios are consistent with the clinical application.

Prescription Use YES
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO
(21 CFR 801 Subpart C)

Indications for Use Form

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Patel
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110875